UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,450	01/26/2001	Lawrence I. Kruse	114309.341	4357

7590 07/23/2002

DAVID S. CHERRY, ESQ.
WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE 46TH FLR.
PHILADELPHIA, PA 19103

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/23/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/769,450	KRUSE ET AL.	
	Examin r	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted May 7, 2002 is acknowledged.

Receipt of the IDS submitted February 8, 2002 is also acknowledged. Note the IDS was filed after the mailing date of the first office action on merit (February 7, 2002). Therefore, a fee would be charged in accordance with § 1.97(c).

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 27-32 are rejected under 35 U.S.C. 112, first paragraph, because of the reasons set forth in the prior office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25, 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "substantially" in claim 25 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the how much the agonist is devoid of central nervous system effects.

Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-2 of U.S. Patent No. 5,763,445, claims16 of U.S. Patent No. 5,598,513, claims1-3 of U.S. Patent No. 6,028,063, claims 1-8 of U.S. Patent No. 6,180,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to method of treating or preventing pruritis by administering compounds known as kappa opioid receptor agonists. The compounds employed in those patented claims are species of kappa opioid receptor agonists. Regarding the particular dosage and the particular administration method, note the optimization of a result effective parameter, e.g., dosage and method for administration of a known pharmaceutical agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 25, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dooley et al. in further view of Lawhorn et al.

7. Dooley et al. teaches a peptide kappa opioid receptor agonist. Dooley further teaches the usefulness of the agonist for treating pruritis, particularly caused by mu receptor agonist, such as morphine, See, particularly, column 2, line 10 bridging to column 3, line 50, and column 5, lines 12-29.

8. Dooley et al. does not expressly teach a method of treating pruritis by administering a non-peptide kappa opioid receptor agonist, or the particular dosage, or the particular method of administration.

9. However, Lawhorn teaches a method for preventing pruritus by administering a non-peptide Kappa receptor agonist (1-3 mg) to a patient for preventing pruritus caused by mu receptor agonist, such as morphine. See, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ a kappa receptor agonist, such as non-peptide, to preventing pruritus caused by mu receptor agonist.

A person of ordinary skill in the art would have been motivated to employ a kappa receptor agonist, such as non-peptide, to preventing pruritus caused by mu receptor agonist,

because non-peptide kappa receptor agonists are known to be similarly useful as peptide kappa receptor agonist. Further, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the kappa opioid receptor agonist of Dooley for treatment of pruritis because it would avoid the side effects caused by other opioid agonist. Regarding the particular dosage and the particular administration method, note the optimization of a result effective parameter, e.g., dosage and method for administration of a known pharmaceutical agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Arguments

Applicants' amendments and remarks submitted May 7, 2002 have been fully considered, but are not persuasive for reasons discussed below.

1. Applicants' remarks regarding the rejection under 35 U.S.C. 112 first paragraph are not persuasive. Particularly, as stated in the prior office action, a person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those 'kappa opioid receptor agonists' within *claimed scope*. Note that the claims encompass any compounds, which may have the property of kappa receptor agonist. . The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the employment of kappa receptor agonist. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only four type of Kappa receptor agonist set forth (see the specification, pages 8-134), thereby failing to provide sufficient working examples. Applicants provide no guidance, direction, or working examples as to compounds other than the four types of compounds disclosed herein. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all Kappa receptor agonist, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

10. Applicants' remarks regarding the rejection under 35 U.S.C. 112, second paragraph are not persuasive. Particularly, while there are extensive teaching regarding opiate and central nervous system side effects in the specification, applicants fail to define clearly the meaning of "substantially". As stated in the prior office action, one of ordinary skill in the art would not be

reasonably appraised of the scope of the invention. The claims are indefinite as to *how much* the agonist is devoid of central nervous system effects.

11. The arguments regarding the rejection under 35 U.S.C. 103 are moot in view of the new ground rejection.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

Shengjun Wang

July 16, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200